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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,803	09/26/2001	Iann Rance	18433/2042	9170
29933	7590	03/04/2004	EXAMINER	
PALMER & DODGE, LLP KATHLEEN M. WILLIAMS 111 HUNTINGTON AVENUE BOSTON, MA 02199			SULLIVAN, DANIEL M	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/963,803

### Applicant(s)

RANCE ET AL.

### Examiner

Daniel M Sullivan

### Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 43-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43-45, 47-64, 66, 68 and 70-80 is/are rejected.
- 7) ☒ Claim(s) 46, 65, 67 and 69 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

This Non-Final Office Action is a reply to the "Amendment and Reply" of 3 December 2003, filed in response to the Non-Final Office Action mailed 3 June 2003. Claims 1-42 were considered in the 3 June Office Action. Claims 1-42 were canceled and claims 43-80 were added in the 3 December Paper. Claims 43-80 are presently pending and under consideration.

#### ***Priority***

Applicant's claim for priority of FR 99/03925 is acknowledged. In view of the clarification of the filing date of PCT/IB00/00370 as 29 March 2000, Applicant is entitled to benefit of the French application once all of the requirements of 119(a)-(d) have been met.

#### ***Response to Amendment***

##### **Specification**

Objection to the abstract and specification as containing minor informalities is withdrawn in view of the filing of a substitute abstract and the amendments to the specification.

##### **Claims**

Objection to and rejection of claims 1-42 is rendered moot by cancellation of the claims.

#### ***New Grounds***

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 43-45, 47-64, 66, 68 and 70-80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention

Claims 43-45, 47-64, 68 and 70-80 are similar in scope to originally filed claims 2-4, 11-17, 19-21, 27 and 29-39 and therefore lack adequate written description for reasons of set forth in the 3 June Office Action. In addition, the rejection is hereby applied to claim 66, which corresponds to originally filed claim 23. Although claim 23 was not previously rejected under 35 U.S.C. §112, first paragraph, upon further consideration, it is clear that the full scope of the subject matter encompassed thereby is not adequately described in the specification. The claim is directed to an isolated promoter nucleic acid sequence comprising a fusion of at least a part of each of the sequences of SEQ ID NO: 1 and SEQ ID NO: 2. The phrase "a part of" is not defined in the specification and, according to common usage, would encompass any portion or fragment of the designated sequences. Thus, the broadest reasonable interpretation of the claim reads on any promoter nucleic acid sequence comprising a fusion of any single nucleotide found in the sequence set forth as SEQ ID NO: 1 with any single nucleotide found in the sequence set forth as SEQ ID NO: 2. In other words, the claim encompasses all promoter nucleic acid sequences.

In response to the rejection of record applicant asserts that the promoter of the amended claims is now limited to being derived from a first plant promoter originating from a Commelina Yellow Mottle Virus comprising a vascular expression promoter which is replaced with a nucleic acid sequence derived from a second plant promoter originating from a Cassava Vein Mosaic Virus comprising a plant green tissue expression promoter region. Applicant urges that the claims are limited to chimeric promoters which originate from a CoYMV virus wherein the plant vascular expression promoter region is replaced with a plant green tissue expression promoter region derived from a CsVM virus.

However, it should be made clear that the claims are not directed to the starting material; Applicant is claiming a derivative wherein, as applicant acknowledges, the derivative can be derived directly or indirectly from the sequence to which it refers by substitution, deletion, addition, mutation, fragmentation, and/or synthesis of one or more nucleotides. Given that there is no limit on the extent to which the starting material can be derivatized, the starting material is irrelevant to the final product, which is what is being claimed. That is, the claims have the same scope regardless of the starting material because one can simply continue the process of derivatization until any given product is obtained. If the claims encompass infinite substitutions, deletions, additions, mutations or fragments of a given starting material, what difference does it make whether that starting material is a plant promoter originating from a CoYMV promoter or adenine?

Applicant asserts that the 12 different species of chimeric promoters disclosed in the specification adequately describe the claimed genus. However, given the tremendous scope of

the claimed derivatives, the disclosure of 12 nucleic acid sequences having closely related sequence clearly fails to describe the full scope of the claimed subject matter.

Applicant's arguments have been fully considered but are not deemed persuasive either individually or as a whole. Therefore, only the described the chimeric promoter wherein the vascular expression promoter from the CoYMV intergenic region promoter is replaced with the green tissue promoter region from the CsVMV intergenic region promoter meet the written description provision of 35 U.S.C. §112, first paragraph.

Claims 43-45, 47-64, 66, 68 and 70-80 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for the chimeric promoter wherein the vascular expression promoter from the CoYMV intergenic region promoter is replaced with the green tissue promoter region from the CsVMV intergenic region promoter, does not reasonably provide enablement for all chimeric promoters wherein a derivative of the vascular expression promoter from the CoYMV intergenic region promoter is replaced with a derivative of the green tissue promoter region from the CsVMV intergenic region promoter. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 43-45, 47-64, 66, 68 and 70-80 are similar in scope to originally filed claims 2-4, 11-17, 19-21, 23, 27 and 29-39 (*Id.*) and therefore lack an enabling disclosure for the reasons set forth in the 3 June Office Action.

In response to the rejection of record, Applicant asserts that the claims are now limited to a chimeric promoter wherein the vascular expression promoter from the CoYMV intergenic

region promoter is replaced with the green tissue promoter region from the CsVMV intergenic region promoter.

However, as discussed above, the claims are not, in fact, limited to a chimeric promoter wherein the vascular expression promoter from the CoYMV intergenic region promoter is replaced with the green tissue promoter region from the CsVMV intergenic region promoter, but are instead limited to a chimeric promoter wherein a derivative of the vascular expression promoter from the CoYMV intergenic region promoter is replaced with a derivative of the green tissue promoter region from the CsVMV intergenic region promoter. Applicant urges that the specification provides 12 different species of the claimed promoter and teaches how to test various derivatives for activity. However, given the tremendous breadth of the claimed subject matter (*Id.*), in order to make and use the full scope of the claimed invention, the skilled artisan would have to construct a widely divergent genus of chimeric promoters without teachings from the specification or prior that would allow for the identification of promoters having the functional characteristics set forth in the claims by any means other than random trial and error experimentation. Furthermore, because the specification and prior art does not teach how the promoters of the claims could be derivatized while maintaining function, the skilled artisan would again have to resort to blind trial and error experimentation to make and test each and every possible derivative for function to identify the embodiments encompassed by the claims. Given the enormous scope of the claims, the amount of experimentation required would clearly be undue.

Applicant's arguments have been fully considered but are not deemed persuasive either individually or as a whole; therefore, the claims are rejected under 35 U.S.C. §112, first paragraph, as lacking enablement for the full scope of the claimed subject matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 50 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite in referring to a "CT promoter element". The Examiner can find no definition of a CT promoter element in the disclosure. In the interest of compact prosecution, the claims have been examined with the assumption that "CT" is a typographical error and should read "GT" as in original claims 14 and 15.

#### ***Allowable Subject Matter***

Claims 46, 65, 67 and 69 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DMS

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